K092291
p1/1

510(k) Summary

AUG 21 2009

SUBMITTER

Submitted on behalf of:	**Company Name:**	**Leonhard Lang GmbH**
	Address:	Archenweg 56 6020 Innsbruck Austria
	Telephone:	++ 43 / 512 / 33 4 25 7
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	Registration Number:	8020045
	Owner/Operator Number:	8020045
	by:	**Elaine Duncan**, MS.M.E., RAC President, Paladin Medical, Inc. PO Box 560 Stillwater, MN 55082 Telephone: 715-549-6035 Fax: 715-549-5380
Contact Person:	**Elaine Duncan**	
Date prepared:	28, July 2009	
Trade Name:	Skintact® ECG Tab Electrodes with KH06D Gel *(and as also to be offered for sale under various private label tradenames)*	
Common Name:	Disposable ECG Electrodes	
Classification Name:	Electrocardiograph (ECG) Electrode	
Regulation:	Electrocardiographic electrode, 21 CFR 870.2360	
Regulatory Class	This device is Class II	
Device Panel and Product Code:	Cardiovascular: 74 DRX	
Reason for 510(k) Submission:	change of material	

Substantial Equivalence: Skintact® ECG Tab Electrodes with KH06D Gel are substantially equivalent to **K030509** "Leonhard Lang Skintact® ECG Electrodes with KH06 Gel" and have the same indication for use. The only change between the original Skintact® ECG Tab Electrodes with KH06 Gel and the Skintact® ECG Tab Electrodes with KH06D Gel is the modification of gel. No new technology is required for this change.

Description of device: All Skintact® ECG Tab Electrodes are self-adhesive, non-sterile, single use disposable electrodes. The Skintact® ECG Tab Electrodes with KH06D Gel are composed of the same materials as the predicate devices by Leonhard Lang except the modified gel.

Indications for use: Skintact® ECG Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording. Skintact® ECG Electrodes are single-use, non-sterile and disposable and are to be used on intact (uninjured) skin.

Basis for Equivalence - performance testing: Biocompatibility testing was cleared and passed ISO 10993 for intact skin. Biocompatibility testing confirms the materials are biocompatible and the change does not introduce new risks. According to the performance data, Leonhard Lang Skintact® ECG Tab Electrodes with KH06D Gel met specifications as established in the standard, ANSI/AAMI EC12:2000/(R)2005, as did the predicate device). The shelf life of Skintact® ECG Tab Electrodes with KH06D Gel was tested in accelerated aging in the same manner as the predicate device K030509. The introduction of the Skintact® ECG Tab Electrodes with KH06D Gel does not introduce new issues of safety or effectiveness and the Skintact® ECG Tab Electrodes with KH06D Gel are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 21 2009

Leonhard Lang, GmbH
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082-0560

Re: K092291
Trade/Device Name: Leonhard Lang Skintact ECG Tab Electrode with KH06D Gel
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (Two)
Product Code: DRX
Dated: July 28, 2009
Received: July 29, 2009

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092291

Indications for Use

510(k) Number (if known):

Device Name: Skintact® ECG Tab Electrodes with KH06D Gel

Indications For Use:

Skintact ECG Electrodes are designed for use in general electrocardiographic procedures where ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include in particular patient ECG surveillance and ECG diagnosis recording.

Skintact ECG Electrodes are single use, non-sterile and disposable and are to be used on intact (uninjured) skin.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092291